K082202

FEB -2 2009

LDR Spine ROI Interbody Fusion System

510(k) Summary of Safety and Effectiveness

SUBMITTED BY	LDR Spine USA 4030 W. Braker Lane, Suite 360 Austin, TX 78759
FOREIGN ESTABLISHMENT REGISTRATION NUMBER	3004788213
US AGENT ESTABLISHMENT REGISTRATION NUMBER	3004903783
CONTACT PERSON	Noah Bartsch Manager, Clinical, Regulatory and Quality Affairs Phone: 512-344-3319 Fax: 512-344-3350
DATE PREPARED	December 2, 2008
CLASSIFICATION NAME	MAX 888.3080- Intervertebral Fusion Device with Bone Graft, Lumbar MQP 888.3060 - Spinal Intervertebral Body Fixation Orthosis
COMMON NAME	Intervertebral Body Fusion Device (MAX) Spinal Vertebral Body Replacement Device (MQP)
PROPRIETARY NAME	LDR Spine ROI Interbody Fusion System

DEVICE DESCRIPTION

The proposed ROI Interbody Fusion System will be offered in two (2) configurations of various sizes. The configurations are designed based on surgical approach, and consist of: 1) ROI-T, transforaminal approach and 2) ROI-A, anterior approach.

INDICATIONS:

When used as an intervertebral body fusion device, the ROI Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

When used as a vertebral body replacement device, The ROI System of implants is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system. These devices are intended to be used with autograft or allograft bone.

The ROI-A implants are intended to be implanted singularly while the ROI-T implants may be implanted singularly or in pairs.

MECHANICAL TEST DATA

Mechanical test results demonstrate that the proposed ROI Interbody Fusion System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2011

LDR Spine USA
% Mr. Noah Bartsch
Manager, Clinical, Regulatory and Quality Affairs
4030 W. Braker Lane, Suite 360
Austin, Texas 78759

Re: K082262
Trade/Device Name: LDR Spine ROI Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX, MQP
Dated: December 2, 2008
Received: December 4, 2008

Dear Mr. Bartsch:

This letter corrects our substantially equivalent letter of February 2, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082262

Device Name: LDR Spine ROI Interbody Fusion System

Indications for Use:

When used as an intervertebral body fusion device, the ROI Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082262